Label, in Part: (Bottle) "Caution—To Be Used Only By Or On The Prescription Of A Physician 25 Tasapan Pearls \* \* \* A carefully prepared combination of pennyroyal, apiol, powdered ext. of ergot, aloin, savin, rue, and vegetable oil in a soft gelatin pearl."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since its labeling failed to reveal the purposes for which the article was to be taken; and, Section 503 (b) (4), the article was a drug which was subject to Section 503 (b) (1) (B), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription." The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: March 24, 1954. Default decree of condemnation and destruction.

## DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\*

4349. Misbranding of pituitary tablets. U. S. v. 1 Bottle \* \* \*. (F. D. C. No. 36288. Sample No. 82555-L.)

LIBEL FILED: January 14, 1954, Western District of New York.

ALLEGED SHIPMENT: On or about August 24, 1953, by Richlyn Laboratories, from Philadelphia, Pa.

PRODUCT: 1 bottle containing 10,000 pituitary tablets at Rochester, N. Y.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it did not state the conditions in which the article was to be used.

Disposition: February 12, 1954. Default decree of condemnation and destruction.

4350. Misbranding of Triulcin tablets. U. S. v. 13 Cases, etc. (F. D. C. No. 36072. Sample No. 50541-L.)

LIBEL FILED: November 4, 1953, Southern District of New York.

ALLEGED SHIPMENT: On or about September 10, 1953, from Newark, N. J.

PRODUCT: Triulcin tablets. 13 cases, containing a total of 86,600 tablets, and 126 cartons, each carton containing 100 tablets and a leaflet entitled "Further Facts About Triulcin," at New Rochelle, N. Y., in possession of S. B. Leonardi & Co., Inc., together with an additional quantity of the leaflets and a number of empty cartons labeled in the same manner as the 126-carton lot.

RESULTS OF INVESTIGATION: When originally shipped from Newark, N. J., the tablets were contained in 15 cases, each containing 140 cellophane strips and each strip containing 50 tablets. Upon receipt of the tablets by the consignee, a portion of the shipment was repackaged into cartons, with the balance of the shipment, consisting of 13 cases, being held for repackaging into the abovementioned empty cartons.

LABEL, IN PART: (Carton) "Triulcin Indicated for relief of stomach Ulcer Pains and discomfort due to excessive stomach acidity 100 Tablets \* \* \* Active Ingredients: Hibiscus Esculentus, Water-soluble Chlorophyllin, Aluminum Hydroxide Gel, Magnesium Trisilicate, Excipients and Flavor. Average Dose: 10 tablets daily—2 on arising, 2 on retiring, and 2 after each meal (at

<sup>\*</sup>See also No. 4348.